DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administratic

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2953656

January 25, 2002

Kevin K. Lee, President
Nor-Cal Seafood, Inc.
2810 E. 7th Street
Oakland, California 94601

WARNING LETTER

Dear Mr. Lee:

On August 31 and November 1 and 5, 2001, we inspected your seafood processing facility, located at 2810 E. 7th Street, Oakland, California. We found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your mud fish, largemouth bass, white eel, red snapper, Atlantic lobster, Mandarin fish, and mackerel to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. We have attached a copy of 21 CFR 123, Fish and Fishery Products, for your ready reference.

Your serious HACCP deviations are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for mackerel and Mandarin fish imported from [redacted]

2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for:

   - mud fish, largemouth bass, and white eel shipped by [redacted] and

- red snapper, Atlantic lobster, Mandarin fish, and mackerel shipped by [redacted]

At the conclusion of the October/November 2001 inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Furthermore, your firm and the foreign processor(s) may be placed on import alert, and future shipments of the product(s) may be subject to detention without physical examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures:
21 CFR 123, Fish and Fishery Products
Form FDA 483